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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,796	07/16/2003	Jack E. Tabaska	38-21(52529)B	3342

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EXAMINER

WHALEY, PABLO S

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 05/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/620,796	TABASKA, JACK E.	
	Examiner	Art Unit	
	Pablo Whaley	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☒ Claim(s) 4-5 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>10/14/03</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

APPLICANT'S ELECTION

Applicant's election of Species I (Kozak Consensus and Frame-Specific Base Composition), Specie II (Bayes Network Score and Frame-specific Monomer Score), and Specie III (net8 and dfm2), with traverse, in the reply filed on 3/1/06 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

CLAIMS UNDER EXAMINATION

An action on the merits of Claims 1-5, as they read on the elected species, follows.

INFORMATION DISCLOSURE STATEMENT

The information disclosure statement filed 10/14/03 has been considered in full.

OBJECTIONS

Claims 4 and 5 have grammatical errors. Claims 4 and 5 recite "...feature variable combination of greater than 0.9." Claims 4 and 5 should read "...feature variable combination greater than 0.9." Appropriate correction is required.

CLAIM REJECTIONS - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-5 are rejected under 35 U.S.C. 101 because these claims are drawn to non-statutory subject matter. Claims 1-5 are directed to a process for “finding translation initiation codons in a nucleotide sequence” which does not recite either a physical transformation of matter nor a practical application (i.e. a concrete, tangible and useful result). Instant claim 1 recites steps drawn to analyzing data, evaluating scoring functions, generating a function, and using said function. As the Specification does not define these to be physical steps, non-physical (i.e. *in silico*) methods of finding translational initiation codons are encompassed by the instant claims. As the steps of claim 1 are interpreted to be nonphysical, the claim does not result in a physical transformation of matter. Where a claim does not recite a physical transformation of matter, it MAY be statutory where it recites a concrete, tangible and useful result. However, no actual, concrete result is recited in the claims, nor is any useful result “produced” in a tangible form useful to one skilled in the art. For these reasons, the claims are not statutory. For an updated discussion of statutory considerations with regard to non-functional descriptive material and computer-related inventions, see the Guidelines for Patent Eligible Subject Matter at 1300 OG 142, Annex IV, Nov. 22, 2005.

CLAIM REJECTIONS - 35 USC §112, 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1-5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for finding initiation codons in a nucleotide sequence using Bayes Network construction in Quadratic Discriminant Analysis, does not reasonably provide enablement for finding initiation codons in a nucleotide sequence using a quadratic discriminant function in Quadratic Discriminant Analysis. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in *Ex parte Forman*, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in *In re Wands*, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a prima facie case are discussed below which leads to the determination that the above

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claim lacks enablement due to undue experimentation being required to make and use the invention.

The instant claims are enabled for Bayes analysis in combination with a discriminant function because the instant specification teaches Bayes Network construction [p.15], and exemplifies how to use a Bayes Network for the statistical characterization of initiator or pseudoinitiator codons in a training set to produce parameters [p.39].

In the instant case, the claimed subject matter, drawn to finding initiation codons in a nucleotide sequence, lacks enablement for the following reasons:

Methods of discriminating data using discriminant analysis models are well-known in the art [Solovyev et al., Zhang et al.]. The instant claims recites steps of “analyzing...to measure a combination of features” to produce a set of numerical values; evaluating scoring functions; generating a quadratic discriminant function; and using a quadratic discriminant function to analyze a second data set to calculate the “probability of an initiator codon at a position” (claim 1). Given the nature of the invention, finding initiation codons in a nucleotide sequence using Quadratic Discriminant Analysis requires a disclosure of a quadratic discriminant function. For example, Zhang et al. use linear discriminant analysis and disclose a linear discriminant function for data classification in their analysis [p.5157, col. 2, Equation 1]. While the instant Specification discloses functions for feature modeling [p.14-17], and scoring functions [p.20], there is no limiting definition of a mathematical formula for a “quadratic discriminant function” as it relates to the specific training parameters (i.e. feature variables, output of scoring functions) required to generate the quadratic discriminant function. Therefore applicants have not made a “full” disclosure of the “quadratic discriminant function” required to practice the claimed subject matter, and have not provided sufficient guidance for “generating a quadratic discriminant function” (instant claim 1, step d). In general, computational methods show a range

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of accuracies for the prediction of coding and intron regions within large regions of uncharacterized genomic DNA at the nucleotide level, with an average fraction of actual exon identification of less than 50% [Zhang et al.]. Despite the high level of skill in the art, one skilled in the art would not know how to determine translation initiation codons in a nucleotide sequence using a quadratic discriminant analysis without knowledge of a specific quadratic discriminant function as it relates to the specific design parameters, therefore it would require undue experimentation by one of skill in the art to predictably practice the full scope of the instantly claimed invention. [Wands factors (1), (2), (4), (5), (6), (7), (8)].

WRITTEN DESCRIPTION

Claim 1-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 recites the limitation "generating a quadratic discriminant function through a selection of a combination of feature variables that optimally classifies ATG triplets in a nucleotide sequence as initiator codons or pseudoinitiator codons based on the output of said scoring functions." The Specification discloses scoring functions applied to training sets to generate feature optimizing these variables, and training "the quadratic discriminant function", and discloses a program developed for detecting initiator codons in sequence data (i.e. Codon I) [p.41-42]. However, neither the instant claims nor the specification provides a written description of a quadratic discriminant function derived for use with the associated optimally selected design parameters (i.e. output of said scoring functions). Therefore, the description lacks sufficient detail as to actual quadratic discriminant function used in the Quadratic Discriminant Analysis, such that

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one of skill in the art would have been aware that applicants were actually in possession of such a function at the time of invention.

CLAIM REJECTIONS - 35 USC § 112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "said scoring function's parameters" (step b). There is lack of antecedent basis for this limitation. Furthermore, the claim is indefinite as it is unclear which parameters are required by the scoring function. Clarification is requested.

Claim 1 recites "using said quadratic discriminant function to analyze...and to calculate...using the output of said analysis" (part d). These are passive steps, therefore it is unclear if applicant intends these to be active, positive limitation steps of the method, or merely intends to recite intended results. It is suggested that applicant re-write these steps to clarify which are intended to be positive active steps. Clarification is requested. Furthermore, as the specification does not define or fully and completely describe a "quadratic discriminant function" for carrying out the intended quadratic discriminant analysis, it is unclear as to the metes and bounds intended by applicant for the claimed quadratic discriminant function" such that one skilled in the art would know which parameters this function consists of. Claim 2-5 are rejected as they depend directly from claim 1.

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CONCLUSION


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pablo S. Whaley

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